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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/813,820	HOOK ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

1. Applicant's amendment and response filed June 13, 2006 are acknowledged. Claims 1-8 have been amended. Claims 9-16 have been cancelled. The Declaration and attached Appendix filed under 37 CFR 1.132 on June 13, 2006 by Dr. Patti is acknowledged.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

3. In view of Applicant's amendment and response the following objections and rejections have been withdrawn:

a) Rejection of claims 1-16 under 35 U.S.C. 112, second paragraph, page 10, paragraph 6 of previous Office action.

b) Rejection of claims 1-16 under 35 U.S.C. 112, second paragraph, page 10, paragraph 7 of previous Office action.

Rejections Maintained

4. The rejection under 35 U.S.C 112, first paragraph (written description) is maintained for claims 1-16 for the reasons set forth on pages 3-6, paragraph 4 of the previous Office Action.

Applicant's Arguments

1). The Written Description Guidelines Training Materials include an example wherein the claim is directed to an isolated antibody capable of binding X and the specification does not teach in an example any antibody. The example concludes that with a well-characterized antigen the specification provides adequate written description.

2). Applicant argues that they go beyond characterization and isolation of the specific antigen, namely M31 subregion at amino acids 61-343 of the collagen binding protein but indeed Applicants' specification actually describes generating antibodies to the M31 region. Thus, Applicants have provided more than an isolation of the antigen targeted by the claimed antibody which in and of itself is sufficient to satisfy the Written Description Guidelines.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed June 13, 2006 have been fully considered and deemed non-persuasive.

1). Contrary to Applicant's assertion, the cited Example is not applicable as the antigen which the antibody is raised is not well-characterized. Applicant has merely recited a span of amino acids within an undefined amino acid sequence. Moreover, Applicant has not describe the immunoepitopes (binding regions) within the recited span

which would give rise it the claimed antibodies. Consequently, Applicant arguments are not persuasive and hence the instant rejection. Applicant has merely defined a region of amino acids along an undisclosed amino acid sequence. Applicant has not describe the immunoepitopes (binding regions) within the undisclosed amino acid sequence. Consequently, said Example is not persuasive to the instant rejection.

2). With regard to point 2, it should be remembered that the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. Applicant has not provided written description for the claimed antibody since the antigen in which the antibody binds has not been well-characterized. The recitation of " the M31 domain of the collagen binding protein having the sequence of amino acids 61-343 of the full-length collagen binding protein of *Staphylococcus aureus*" does not constitute a "well-characterized antigen". The specification fails to disclose what said collagen binding protein. The specification is equally silent regarding which amino acid residues within said collagen binding protein (or M31 domain) are essential for antibody binding (i.e. which amino acids form immunoepitopes). Therefore, the specification fails to adequately describe at least a substantial number of members of the genus of antibodies to which the claims refer; and accordingly the specification fails to adequately describe at least a substantial number of members of the claimed genus of antibodies.

Moreover, it should be noted that the courts have recently decided in Randolph J. Noelle v Seth Lederman, Leonard Chess and Michael J. Yellin (CAFC, 02-1187, 1/20/2004) that: a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. See Enzo Biochem II, 323 F.3d at 965; Regents, 119 F.3d at 1568. Therefore, based on our past precedent, as long as an applicant has disclosed a "fully characterized antigen," either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen.

Noelle did not provide sufficient support for the claims to the human CD40CR antibody in his '480 application because Noelle failed to disclose the structural elements of human CD40CR antibody or antigen in his earlier '799 application. Noelle argues that because antibodies are defined by their binding affinity to antigens, not their physical structure, he sufficiently described human CD40CR antibody by stating that it binds to human CD40CR antigen. Noelle cites Enzo Biochem II for this proposition. This argument fails, however, because Noelle did not sufficiently describe the human CD40CR antigen at the time of the filing of the '799 patent application. In fact, Noelle only described the mouse antigen when he claimed the mouse, human, and genus forms of CD40CR antibodies by citing to the ATCC number of the hybridoma secreting the mouse CD40CR antibody. If Noelle had sufficiently described the human form of CD40CR antigen, he could have claimed its antibody by simply stating its binding

affinity for the "fully characterized" antigen. Noelle did not describe human CD40CR antigen. Therefore, Noelle attempted to define an unknown by its binding affinity to another unknown. As a result, Noelle's claims to human forms of CD40CR antibody found in his '480 application cannot gain the benefit of the earlier filing date of his '799 patent application.

Moreover, Noelle cannot claim the genus form of CD40CR antibody by simply describing mouse CD40CR antigen. In view of all the above, the rejection is maintained.

The rejection as set forth in the previous Office action is reiterated below:

The rejection was on the grounds that claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-8 are drawn to an isolated antibody that binds to the specific M31 subregion of a collagen binding domain having the sequence of amino acids 61-343 of the full length collagen binding protein of *Staphylococcus aureus* wherein said antibody prevents *S. aureus* infection.

Claims 9-12 are drawn to an isolated antibody that binds to the specific M31 subregion of a collagen binding domain having the sequence of amino acids 61-343 of the full length collagen binding protein of *Staphylococcus aureus* wherein said antibody treats *S. aureus* infection.

The claims are drawn to a vast genus of antibodies. To fulfill the written description requirements set forth under 35 USC,112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alliteratively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention.

To adequately describe the claimed genus of antibodies, Applicant must adequately describe the antigenic determinants (immunoepitopes) that elicit an immune response directed against *Staphylococcus aureus* not just those determinants that would elicit an immune response to the polypeptide since a given polypeptide can be

immunogenic but not induce an directed immune response (i.e. immune response to *S. aureus*).

The specification, however, does not disclose distinguishing and identifying features of a representative number of members of the genus of antibodies to which the claims are drawn, such as a correlation between the structure of the immunoepitope and its recited function (to elicit an immune response directed against *S. aureus*), so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus of immunogenic compositions. Moreover, the specification fails to disclose which amino acid residues are essential to the function of the immunoepitope or which amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent, or by which other amino acids the essential amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent. Therefore, since the specification fails to adequately describe at least a substantial number of members of the genus of immunoepitopes to which the claims are based. It should be noted that antibodies provide (at best) passive immunity and the specification fails to adequately describe any member of the claimed genus of antibodies capable of stimulating an immune response in an animal to *S. aureus* (either prophylactically or therapeutically).

MPEP 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention.* The invention is, for the purposes of the "written description" inquiry, *whatever is now claimed.*

See Vas-cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 17 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC j 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. M Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 US. C. 112, paragraph 1, "'Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, [p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (Id. at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a

representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed.

5. The rejection under 35 U.S.C 112, first paragraph (enablement) is maintained for claims 1-2 for the reasons set forth on pages 6-9, paragraph 5 of the previous Office Action.

Applicant's Arguments

1). Applicant argues that the rejection is moot in light of the present amendments directed to the claims to the specific antibodies that bind to the M31 subregion.

2). Applicant argues that these antibodies have been disclosed in Applicants' specification and have been shown to be useful by virtue of the fact that the use of these antibodies improved the survival of treated mice.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed June 13, 2006 have been fully considered and deemed non-persuasive.

1). Contrary to Applicant's assertion, the amended claims do not obviate the rejection. It should be noted that claim 2 recites "...wherein said antibody prevents *S.*

aureus infection in humans". Thus, the functional limitation of preventing infection is still within the scope of the claims.

2). With regard to point 2, it should be remembered that the term "prevents" encompasses the ability of the specific antigen to induce protective immunity to *Staphylococcus aureus* infection or disease induction. The specification fails to provide evidence that any of the claimed antibodies are capable of inducing protective immunity. This demonstration is required for the skilled artisan to be able to use the claimed antibodies for their intended purpose of preventing *S. aureus* infections. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced. Therefore, Example 6, page 106 of the instant specification only refers to treatment of mice and not humans. Thus, the instant specification does not support the recited limitation of "... wherein said antibody prevents *S. aureus* infection in humans".

The rejection as set forth in the previous Office action is reiterated below:

The rejection was on the grounds that claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to an isolated antibody that binds to the specific M31 subregion of a collagen binding domain having the sequence of amino acids 61-343 of the full length collagen binding protein of *Staphylococcus aureus* wherein said antibody prevents or treats *S. aureus* infection.

The specification teaches that the antibodies of the invention may be useful in treatment of *Staphylococcus aureus* infections (page 5). The instant specification teaches that antisera raised against and reactive with collagen binding protein (CBP) inhibits binding, promotes phagaocytosis and enhances intracellular killing by macrophages (page 19). Therefore, the specification contemplates that the administration of antibodies reactive with CBP to at-risk subjects will be effective for

prophylaxis of and in the case of infected subjects for therapy of bacterial infection (pages 19-20).

However, the fails to teach which, if any, antibodies are effective to prevent *S. aureus* infections. It should be noted that the term "prevents" encompasses the ability of the specific antigen to induce protective immunity to *Staphylococcus aureus* infection or disease induction. The specification fails to provide evidence that any of the claimed antibodies are capable of inducing protective immunity. This demonstration is required for the skilled artisan to be able to use the claimed antibodies for their intended purpose of preventing *S. aureus* infections. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced.

The instant specification fails to demonstrate antibodies of the invention that bind to the M31 subregion of the collagen binding domain having the sequence of amino acids 61-343 of the full length collagen binding domain of *S. aureus* wherein the antibody treats or prevents infection cause by *S. aureus*. Example 6 of the instant specification discloses that when mice with sepsis was administered epitopes containing amino acids 61-343 of the full length CBP and challenged with *S. aureus* only 2 out of 14 mice survived. Moreover, the instant specification only discloses the administration of the "M31 subregion of the collagen binding domain having the sequence of amino acids 61-343 of the full length CBP (i.e. the protein administered) but not a single example of administering the claimed antibody in order to protect against *S. aureus* infection (i.e. induce passive immunity). It should be noted that the claims are directed to antibodies that are capable of treating or protecting *S. aureus* infections and not just to bind the epitope itself.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Claims 1-8 recite the limitation "wherein said antibody prevents *S. aureus* infection". Hence, the instant claims encompass the ability of the claimed antibody to induce protective immunity to *Staphylococcus aureus infection* or disease induction. The prior art teaches that not all antibodies raised against S. aureus proteins are protective. This is evidenced by Nemeth et al *(Infection and Immunity 1995)*, vol. 63, No. 2, p. 375-38) disclose that antibodies to capsular polysaccharides are not protective against *S. aureus* endocarditis (see the Abstract).

Claims 9-16 recite the limitation "wherein said antibody treat *S. aureus* infection". The instant specification does not teach a single working example that discloses administering the claimed antibody in order to treat against *S. aureus* infection. It should be noted that the claims are directed to antibodies that are capable of treating *S. aureus* infections and not just to bind the epitope itself.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to administering an antibody to a subject with a *S. aureus* infection would achieve a desire level of success of preventing *Staphylococcus* infection or disease, 3) there are no working examples which suggest that antibodies raised against the M31 subregion the collagen binding domain hiving sequence of amino acids 61-343 is successful in treating or protecting against *S. aureus* infections and 4) the relative skill of those in the art is commonly recognized as quite high (post - doctoral level).

In view of all of the above, it is determined that the specification has not provided guidance that would enable one of skill in the art to be able to make and use the claimed invention commensurate with the claims. One of skill in the art would require undue experimentation to determine whether the claimed antibody can be used to treat or protect against S. *aureus* infection or diseases.

6. The rejection of claims 1-16 under 35 U.S.C 102(a) as anticipated by Patti et al *(The Journal of Biological Chemistry, 1995, Vol. 270, No. 20, p.. 12005-12011)* is maintained for the reasons of record.

Applicant's Arguments

1). Applicant argues that Patti et al do not teach the claimed isolated antibodies. Applicant argues that Patti et al do not teach an antibody can bind to the M31 subregion defined as amino acids 61-343 of the collagen binding protein of *S. aureus*.

2). Applicant argues that the M31 subregion as recited in the claims is different from the subregion recited in Patti et al. Applicant argues that the prior art discloses the isolation of M17 subregion (amino acids 151-297) whereas the instant claims are drawn to antibodies against subregion M31 amino acids 61-343. Consequently, Patti

et al do not disclose an antibody that can bind to the M31 subregion amino acids 61-63 of the collagen binding protein of *S. aureus*.

3). The Declaration submitted by Dr. Patti show that antibodies generated against the M55 subregion of the collagen binding protein of *S. aureus* (amino acids 50-329) did not all recognize the native receptor even though the native receptor would have included the lesser M55 region which is the collagen binding domain of the collagen binding protein. Applicant argues that a number of these antibodies did not recognize the M31 region.

4). Antibodies generated against one particular subregion of the collagen binding protein do not necessarily recognize larger regions or lesser included regions and thus the Examiner's assumption that Patti et al teach the claimed invention is not true.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed June 13, 2006 have been fully considered and deemed non-persuasive.

1) With regard to points 1-2, it is the Examiner's position that Patti et al teach antibodies that are the same as those of the claimed invention.

2) With regard to point 2, it is the Examiner's position that since subregions M17 and M31 differ by 90 and 44 amino acids at the flanking regions, they would share at least one immunoepitope in the span of 148 amino acids they share. Therefore, barring evidence to the contrary, the skilled artisan would expected that that antibodies

that bind to the M17 subregion would also bind to the overlapping amino acid segments also present in the M31 subregion.

3) With regard to point 3, Applicant's Declaration is insufficient to overcome the prior art rejection. As the presented data show that the antibody generated to the M17 region (antibody unidentified) bound to the M31 subregion though with less efficiency. It should be noted that the presented data showed one antibody for each region. However, this is not commensurate in scope with the instant claims. Moreover, the Declaration is silent as to how said antibodies were raised and selected. Additionally, the only antibody that was correlated with a specific region was 16H9. Finally, point 4, it should be noted that the declaration states that M55 is amino acids 50-329 and is therefore smaller than M31 (amino acids 61-343, subregion recited in the claims). However, according to the specification and the appendix, subregion M55 is amino acids 30 to 529 (SEQ ID No.6) which is a larger region than M31.

In view of all the above, Applicant has not shown that the prior art reference does not anticipate the claimed invention. Thus, the rejection is maintained.

The rejection as set forth in the previous Office action is reiterated below:

The rejection was on the grounds that Patti et al teach polyclonal antibodies raised against the collagen adhesion of *S. aureus* (page 12005). Patti et al teach that the antibodies were raised against the M31 collagen binding segments since the antibodies were raised against amino acids 151-297 of the collagen binding domain (page 12006). Patti et al also teaches a monoclonal antibody raised against the collagen binding domain (page 12007). Claim limitations such as "wherein said antibody prevents *S. aureus* infection, "wherein said antibody prevents *S. aureus* infection in a human" and "wherein said antibody is suitable for parenteral, oral, intranasal, subcutaneous or intravenous administration to an animal" are being viewed as limitations of intended use. The claimed antibodies and the antibodies of the prior art

would be necessarily the same since they were raised using the same antigen, absence evidence to the contrary. Thus, the claimed antibodies and the antibodies of the prior art would have the same biological and immunological properties. The claim limitation "wherein the M31 subregion is encoded by a nucleic acid having the sequence of SEQ ID NO:3" would be inherent in teachings of the prior art since the claimed antibodies and the antibodies of the prior art were raised against the same antigen and hence they necessarily have the same sequence. Furthermore, discovery of a new property for a known product is not patentable. See MPEP 2112.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

New Grounds of Rejection Necessitated by Amendment

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 6 and 8 recite the term "the isolated antisera". It is unclear as to what the applicant is referring. Which particular antisera is Applicant referring to is there more than antisera? Antisera cannot contain an "isolated antibody". Antisera, by definition contains multiple clonal species of antibodies. Correction/clarification is required.

Status of Claims

8. No claims allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vanessa L. Ford
Biotechnology Patent Examiner
August 23, 2006

ROBERT A. ZEMAN
PRIMARY EXAMINER